

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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| VENTANA MEDICAL SYSTEMS, INC., |) | |
| |) | |
| Plaintiff, |) | |
| v. |) | C.A. No. 05-CV-10614-GAO |
| |) | |
| VISION BIOSYSTEMS INC., |) | |
| |) | |
| Defendant. |) | |
| _____ |) | |

**VISION BIOSYSTEMS INC.'S LOCAL RULE 56.1
STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF ITS
MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT**

Robert J. Muldoon, Jr. (BBO #359480)
Pamela Zorn Adams (BBO #640800)
SHERIN AND LODGEN LLP
101 Federal Street
Boston, MA 02110
(617) 646-2000

Of Counsel:
Walter E. Hanley, Jr. (*pro hac vice*)
KENYON & KENYON LLP
One Broadway
New York, NY 10004
(212) 425-7200

Douglas E. Ringel (*pro hac vice*)
John R. Hutchins (*pro hac vice*)
KENYON & KENYON LLP
1500 K Street, N.W.
Washington, DC 20005
(202) 220-4200

Attorneys for Vision BioSystems, Inc.

Pursuant to Local Rule 56.1, in support of its Motion for Summary Judgment of Non-Infringement against Ventana Medical Systems, Inc. (“Ventana”), Vision BioSystems Inc. (“Vision”) submits that there is no genuine issue to be tried with respect to the following facts:

I. The ’861 Patent and Its Prosecution History Demonstrates that Ventana Surrendered Any Claim to Methods that Do Not Use Slide Bar Codes

1. Ventana is asserting only claims 1, 2, 3, 5, 6 and 8 of U.S. Patent No. 6,352,861 (“the ’861 patent”) against Vision’s Bond instruments. (Ex. 22¹, *Ventana’s Responses to Vision’s First Set of Interrogatories*, Response to Interrogatory No. 1). Ventana is listed as the assignee on the cover page of the ’861 patent. (Ex. 1, U.S. Patent No. 6,352,861, cover page.)

2. Claim 1 in the ’861 patent, and all claims that depend therefrom, which include claims 2 and 3, contain the following claim element: “**reading a slide bar code** placed on the slide using the bar code reader thereby acquiring slide information, the slide information indicating reagents to be applied to the slide.” (Ex. 1, U.S. Patent No. 6,352,861, col. 25:2-5 (emphasis added)).

3. Claim 5 in the ’861 patent, and all claims that depend therefrom, which include claims 6 and 8, contain the following claim element: “**reading the slide bar code** on the at least one slide.” (Ex. 1, U.S. Patent No. 6,352,861, col. 25:31 (emphasis added)).

4. The ’861 patent was issued by the U.S. Patent & Trademark Office from U.S. Patent Application 09/452,309 (“the ’309 application”), filed on December 1, 1999. (Ex. 1, U.S. Patent No. 6,352,861, cover page.)

¹ All Exhibit numbers refer to the exhibits attached to the Declaration of John R. Hutchins in Support of Vision’s Motion for Summary Judgment of Non-Infringement.

5. The '309 application was filed as a continuation application and claimed priority from related U.S. Patent Application 07/488,601 ("the '601 application"), which was filed on March 2, 1990. (Ex. 1, U.S. Patent No. 6,352,861, col. 1:4-11.)

6. The '309 application was originally filed with claims 1 through 71, which were the original claims of the '601 application. On August 15, 1997, Ventana submitted a preliminary amendment in the '309 application canceling claims 1 through 71 and adding claims 72 through 113. (Ex. 2, 8/15/97 Preliminary Amendment.)

7. Claim 72 of the '309 application, and all claims that depend therefrom, which include claim 80, contain the following claim element: "**automatically determining** whether reagent in the reagent container should be dispensed onto the slide." (Ex. 2, 8/15/97 Preliminary Amendment, pp. 2-4 (emphasis added)).

8. Claim 80 of the '309 application depends from claim 72 and contains the following claim elements: "wherein the **step of automatically determining** whether reagent in the reagent container should be dispensed onto the slide includes the steps of: providing a bar code reader; **reading a slide bar code** placed on the slide using the bar code reader thereby acquiring slide information, and the slide information indicating reagents to be applied to the slide." (Ex. 2, 8/15/97 Preliminary Amendment, pp. 3-4 (emphasis added)).

9. During prosecution of the '309 application, on May 10, 2001, the patent examiner of the U.S. Patent & Trademark Office ("PTO") rejected claims 72 and 80 as unpatentable under 35 U.S.C. §103 as being an obvious combination of Stark *et al* (*J. Immunol. Methods* 107:89-92 (1988)) (Ex. 8, the "Stark reference") in view of U.S. Patent No. 4,346,056 to Sakurada (Ex. 9, the "Sakurada reference" or "Sakurada") or U.S. Patent No. 5,439,645 to Saralegui *et al* (Ex. 10, the "Saralegui reference" or "Saralegui"). (Ex. 3, 5/10/01 Office Action, p. 4.)

10. In its May 10, 2001 Office Action, the PTO Examiner stated that “Stark *et al* disclose an automatic method and apparatus,” but does not disclose “detecting positions of slide samples or reagent containers, or a bar code reader for identifying types of reagents.” (*Id.*)

11. The May 10, 2001 Office Action, however, further stated that the Sakurada reference discloses reagents “which are detected and identified by sensors [at] column 3, lines 20-31, column 4 line 3 – column 6, line 7, Figs. 3, 5.” (*Id.*) The citation to Sakurada that the PTO Examiner pointed to at column 4 reads in part as follows: “to each reagent vessel 7 ... is attached a label 33 as shown in FIG. 3. The label 33 is provided thereon with **code marks** corresponding to the kinds of reagents contained in the reagent vessel 7 and to analysis item, for example, “**GOT**”. The detector 31 functions to photoelectrically read out these **code marks**.” (Ex. 9, U.S. Patent No. 4,346,056 to Sakurada, col. 4:3-9; Fig. 3 (emphasis added)).

12. The May 10, 2001 Office Action referenced Saralegui as disclosing “sample containers comprising **bar code labels** for identifying the appropriate process for the sample.” (Ex. 3, 5/10/01 Office Action, p. 5 (emphasis added)). Saralegui discloses “bar code indicia label 42.” (Ex. 10, U.S. Patent No. 5,439,645 to Saralegui, col. 4:13).

13. On June 26, 2001, Ventana submitted a response to the PTO Examiner’s May 10, 2001 Office Action and argued that the Stark and Sakurada references did not meet the limitations in claim 72 requiring “automatically determining”:

Stark does not teach or even suggest **automatically determining** whether reagent in the reagent container should be dispensed onto the slide. Rather, Stark only teaches that the slides must be **manually** inserted in the proper positions Sakurada does not disclose, or even suggest, **automatically determining**, based at least in part on information from the slide, whether reagent in the reagent container should be dispensed onto the slide.

(Ex. 5, 6/26/01 Amendment, pp. 10-11 (emphasis added)).

14. In its June 26, 2001 Amendment, Ventana stated, with respect to the Saralegui reference, that it was not prior art:

The Saralegui reference has a filing date of January 25, 1993. As discussed above, the current invention claims a filing date of March 2, 1990. Therefore, the Saralegui reference is not prior art to the present invention.

(Ex. 5, 6/26/01 Amendment, p. 11).

15. On August 13, 2001, after fully considering Ventana's arguments in its June 26, 2001 Amendment, the PTO Examiner issued a Final Office Action rejecting Ventana's arguments regarding Stark in view of Sakurada. The Examiner did adopt Ventana's position that Saralegui was not prior art. (Ex. 6, 8/13/01 Office Action, pp. 2-3). In that Final Office Action, the PTO Examiner again rejected claim 72, which required only "automatically determining" the reagents to apply, under 35 U.S.C. §103 as being an obvious combination of Stark in view of Sakurada, which disclosed labels with "code marks." *Id.* In rejecting claim 72, the Final Office Action did not cite the Saralegui reference. *Id.*

16. In the August 13, 2001 Final Office Action, the PTO Examiner withdrew the rejection of claim 80, which recites "bar codes" in its claim elements, and the citation of the Saralegui reference, which disclosed labels with "bar codes," as prior art. (Ex. 6, pp. 2-3). The Examiner stated that claim 80, unlike claim 72, recited allowable subject matter:

The following is a statement of reasons for the indication of allowable subject matter: . . . While numerous slide staining apparatus and methods exist, none of the prior art teaches or suggest providing a plurality of reagent containers in reagent support wherein each of the reagent container have a reagent **barcode**. The apparatus also providing slides on a slide support, each of the slides having at least one slide **bar code**. Wherein the apparatus provides a barcode reader for reading the **bar codes** on the reagent containers, determining reagents in the reagent containers based on the reading of the **bar codes**. Thereafter, the barcode reader reading the

slide **bar codes** and determining the sequence of reagent to be applied on the slides base upon the reading of the slide **bar codes**.

(Ex. 6, p. 6 (emphasis added)).

17. On August 28, 2001, Ventana responded to the Final Office Action by canceling claim 72, and rewriting dependent claim 80 into independent form by adding all of the limitations of claim 72 into claim 80. (Ex. 7, 8/28/01 Amendment, pp. 1-3). Ventana's August 28, 2001 Amendment did not include any argument against the Final Office Action's rejection of claim 72 under 35 U.S.C. §103 as being an obvious combination of Stark in view of Sakurada. Instead, Ventana's response indicated its intent "to prosecute these [canceled] claims in a continuation application." (*Id.*, p. 2.)

18. The '309 application was subsequently allowed and issued as the '861 patent. Claim 80 of the '309 application became claim 1 of the '861 patent. Claim 88 of the '309 application became claim 5 of the '861 patent. (Ex. 1, U.S. Patent No. 6,352,861, cover page)

II. The Bond-OCR Devices at Issue in this Case Do Not Use Slide Bar Codes

19. This Court ruled on summary judgment in C.A. No. 03-CV-10391-GAO that Vision's prior Bond instruments, which used bar codes on slides, infringed the '861 patent claims. (D.I. 103).

20. Vision redesigned its Bond instruments by using slide labels with slide identifiers that are alphanumeric, *i.e.*, a series of letters and/or numbers. These alphanumeric labels are placed on the slides, and the labeled slides are loaded into the instrument's processing module. When a staining run is started, an imager captures an image of each slide label and sends it to a host computer. The alphanumeric characters on the slide label are then recognized by the computer using Optical Character Recognition ("OCR"). The redesigned Bond instruments ("Bond-OCR") do not print bar codes on slide labels. (Barrow Decl., ¶¶ 3-5).

21. If the host computer of the Bond-OCR is unable to automatically identify a slide—such as if the label is skewed—the slide can still be identified by the operator of the Bond-OCR. The Bond-OCR system software displays an image of the human readable, alphanumeric label on the host computer screen. The operator can then read the displayed image and manually identify the slide to the computer and, thus, the “Bond-OCR” provides operators with the ability to continue a run even if the instrument cannot automatically recognize a slide label. (Barrow Decl., ¶ 6).

III. Ventana’s Recent Attempts at the PTO to Broaden Its Patent Claims to Include Methods that Use OCR as Well as Slide Bar Codes Highlights that: (1) the ‘861 Patent Claims Are Limited to Methods Using Slide Bar Codes; and (2) Ventana Could Have Amended the ‘861 Patent During Prosecution to Expressly Include OCR Slides, But Did Not

22. On January 22, 2002, Ventana filed application 10/054,535 (“the ‘535 application”) as a continuation of the ‘309 application with a new claim 72 that similarly recited the claim element of “automatically determining” the reagents to dispense. (Ex. 11, 1/22/02 Preliminary Amendment to the ‘535 application, pp. 2-3). Ventana’s ‘535 application also submitted dependent claim 73 reciting automatically determining the reagents by “identifying information from the slide,” and dependent claim 75 requiring a slide “barcode.” (*Id.*).

23. During prosecution of the ‘535 application, the PTO Examiner rejected claims 72 and 73, but eventually allowed claim 75. (Ex. 12, 10/30/02 Office Action, p. 2; Ex. 13, 7/29/02 Office Action, p. 3; Ex. 14 4/22/04 Final Office Action, p. 2 (rejecting claims 72 & 73) and p. 4 (allowing claim 75 if rewritten in independent form)).

24. In response to the April 22, 2004 Final Office Action in the prosecution of the ‘535 application, Ventana canceled claims 72 and 73, and rewrote claim 75—reciting a slide “barcode”—in dependent form to gain allowance, and the ‘535 application matured into U.S. Patent No. 6,943,029. (Ex. 17, U.S. Patent No. 6,943,029, claim 1, line 64 (“barcode”)). The only difference between rejected claim 73 and allowed claim 75 (issued claim 1 of the ‘029 patent) was one word—“barcode.” (*See* Ex. 15, comparing rejected claim 73 to issued claim 1).

25. On November 17, 2004, Ventana filed yet another application, 10/991,050 (“the ’050 application”) as a continuation of the ’309 application with a new claim 72 that recited the step of automatically determining the reagents by reading an “optically-coded identifier” on the slide. (Ex. 16, 11/17/04 Preliminary Amendment, p. 4). In its November 17, 2004 Preliminary Amendment, Ventana also amended its specification to refer to prior U.S. Patent 5,235,167, a patent that described both “bar codes” and “optical character recognition.” (Ex. 16 at 2; Ex. 18, col. 15, lines 52-61). In its November 17, 2004 Preliminary Amendment, Ventana stated that the reference to U.S. Patent 5,235,167 was “to reflect the state of the art of barcodes and equivalent identifiers as of the earliest claimed filing date of the present application.” (Ex. 16 at 10). The ’050 application claims priority upon related ’601 application, which was filed on March 2, 1990. (Ex. 16 at 2.)

26. On March 8, 2005, Ventana filed another preliminary amendment in the ’050 application to amend and add claims to recite “text” or “textual information.” (Ex. 21, 3/8/05 Second Preliminary Amendment, pp. 2-9) (amending claims 74, 75, 83, 86 and 93, and adding new claims 108, 109, 111, 113 and 115-118). In its remarks, Ventana stated that it was submitting the Second Preliminary Amendment to “more clearly claim what it is that the Applicant’s regard as their invention. Specifically, the applicant’s have included text as an optical identifier in the claims.” (Ex. 21 at 9).

Respectfully submitted,

Dated: June 18, 2007

/s/ Pamela Zorn Adams

Robert J. Muldoon, Jr. (BBO #359480)

Pamela Zorn Adams (BBO #640800)

SHERIN AND LODGEN LLP

101 Federal Street

Boston, MA 02110

Attorneys for Vision BioSystems Inc.